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| APPLICATION NO.   | FILING DATE              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|--------------------------|----------------------|---------------------|------------------|
| 10/725,619  | 12/02/2003               | Rex Lewis Pitcher    | 3346.2.1            | 4978             |
| 28049 75<br>PATE PIERCE &   | 590 04/03/200<br>& BAIRD | EXAMINER             |                     |                  |
| 215 SOUTH STATE STREET, SUITE 550<br>PARKSIDE TOWER<br>SALT LAKE CITY, UT 84111 |                          |                      | GILBERT, SAMUEL G   |                  |
|   |                          |                      | ART UNIT            | PAPER NUMBER     |
|   |                          |                      | 3735                |                  |
| *   |                          |                      |                     | v=v              |
| SHORTENED STATUTORY   | PERIOD OF RESPONSE       | MAIL DATE            | DELIVERY MODE       |                  |
| 2 MONT  | TUC                      | 04/02/2007           | DAT                 | DED              |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary  |  | Application No.       | Applicant(s)       |  |  |  |
|--|--|-----------------------|--------------------|--|--|--|
|  |  | 10/725,619            | PITCHER, REX LEWIS |  |  |  |
|  |  | Examiner              | Art Unit           |  |  |  |
|  |  | Samuel G. Gilbert     | 3735               |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply |                       |                    |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).   |  |                       |                    |  |  |  |
| Status   |  |                       |                    |  |  |  |
| 1)   | Responsive to communication(s) filed on  |                       |                    |  |  |  |
|  |  | action is non-final.  |                    |  |  |  |
| •  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is    |                       |                    |  |  |  |
| ,  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.                  |                       |                    |  |  |  |
| Dispositi  | on of Claims   |                       |                    |  |  |  |
| 4)⊠  | Claim(s) <u>1-21</u> is/are pending in the application.  |                       |                    |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                       |                    |  |  |  |
|  | 5) Claim(s) is/are allowed.  |                       |                    |  |  |  |
|  | 6) Claim(s) 1-21 is/are rejected.  |                       |                    |  |  |  |
|  |  |                       |                    |  |  |  |
|  | Claim(s) are subject to restriction and/or   | election requirement. | ·                  |  |  |  |
|  | on Papers  |                       |                    |  |  |  |
|  |  |                       |                    |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |                       |                    |  |  |  |
| 10)⊠ The drawing(s) filed on <u>02 December 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.  |  |                       |                    |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |                       |                    |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                       |                    |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                       |                    |  |  |  |
| Priority u   | nder 35 U.S.C. § 119   |                       | •                  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> </ul>  |  |                       |                    |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>   |  |                       |                    |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |                       |                    |  |  |  |
| * S  | * See the attached detailed Office action for a list of the certified copies not received.                         |                       |                    |  |  |  |
| The second secon |  |                       |                    |  |  |  |
|  |  |                       |                    |  |  |  |
| Attachment(s)  |  |                       |                    |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date   |  |                       |                    |  |  |  |
| 3) 🔯 Inform  | ) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application                         |                       |                    |  |  |  |
| Paper  | No(s)/Mail Date <u>3/29/2004</u> .   | 6)                    |                    |  |  |  |

#### **DETAILED ACTION**

## Specification

The abstract of the disclosure is objected to because it exceeds 150 words and includes legal language such as "comprising" line 2. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities: on page 16 line 8 "35 any" is indefinite.

Appropriate correction is required.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lederer.

Claim 1 - element -4- is a chamber, element -5- is a vacuum source, and compression ring -1- and attached sleeve -6- is a membrane sealingly connected to the chamber and supports and applies pressure to the penis, column 2 lines 70-79.

- Claim 2 element -6- is substantially cylindrical in shape.
- Claim 3 portions -2- and -3- form a seal with the chamber and the distal end of sleeve -6- is open.
  - Claim 4 the sleeve -6- is capable of performing the recited functional language.
- Claim 13 a step of providing a chamber -4-, an evacuation device -5-, and a membrane -1- and -6- is set forth, the interior passage of the membrane is occluded the vacuum device is operated and the soft tissue is expanded in both directions. The claim includes descriptive language regarding the membrane, which includes "a second end extendable into the chamber a length greater than the length of a member comprising

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soft tissue." The examiner believes the sleeve -6- is extendable into the chamber a length greater than the length of a member comprising soft tissue. The claim does not set forth the length of the soft tissue or the length of the membrane and while they may be relative there is soft tissue that does not extend into the chamber to a length greater then the membrane. Further, there is no step of inserting the soft tissue into the membrane wherein the soft tissue fully extended is contained within the membrane.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Vollrath(5,951,460).

Element -140- is a vacuum tube, element -200- is a vacuum source, element -80- is a sealing membrane as shown in Figure 8 include a cylindrical shape -120-a tapered portion -112- and a rolled flange -100-. Element -30- is a bushing, a portion of bushing -33- is positioned inside the tube, and portion -32- is outside the tube, which includes a lip to preclude the insertion of the bushing completely inside the tube.

Claim 9 - the bushing is made from a synthetic natural rubber, column 7 lines 43-48 which the examiner is considering an elostomeric material.

Claim 11 - The lip forms an abdominal seal as shown in figure 25.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wysor et al (6,183,414, hereinafter Wysor) in view of Lederer (1,225,341).

Claim 13 - Wysor teaches a method for exercising a male or female organ including providing a chamber, a pump assembly -11-, occluding the interior passageway, operating the vacuum device, drawing the member into the interior passageway and expanding the member radially and axially. However while the chamber set forth in Wysor inherently requires a sealing membrane a membrane extending into the chamber is not set forth. Lederer sets forth a device including a membrane having a sleeve extending into the chamber. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use the chamber -4- and membrane -1-,-6- of Lederer in place of the chamber and membrane of Wysor, which may have been the chamber set forth by Osborne et al(5,421,808) to provide a sleeve which provides an advantage of supporting the penis as set forth in column 2 lines 70-72 of Lederer. Further, Lederer indicates any air pump may be used with the chamber of Lederer, column 2 lines 65-67.

Claim 14 - in the method of Wysor the vacuum is maintained for a time selected to promote vascular expansion as claimed, column 4 lines 39-43.

Claim 15 - the vacuum is released column 4 lines 42 and 43.

Claim 16 - vascular contraction and blood flow is promoted reverts to a flaccid state.

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Claim 17 - repeating the treatment is shown in figure 3 by steps A-I separated by periods of rest "R".

Claim 18 - the number of times the cycle is repeated may be predetermined, see abstract and the results are designed to promote permanent expansion, column 5 lines 14-25.

Claim 19 - sleeve -6- will modify the pressure as claimed.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wysor et al (6,183,414, hereinafter Wysor) and Lederer (1,225,341) as applied to claims 13-19 above, and further in view of Vollrath (5,951,460). The combination set forth above teaches a method as claimed but does not include the use of a gel sealant or lubricant. Vollrath sets forth that the use of gel lubricant/sealants are old and well known in the medical arts, column 1 lines 34-36. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to include the step of applying a gel lubricant/sealant as set forth in Vollrath to aid in the sealing and lubricating the membrane and users body. The examiner is considering the male genitals as set forth in Vollrath includes the abdominal wall at the base of the penis because the membrane generally seals around the penile shaft and with the abdominal wall. The lubricant would promote axial motion.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,243,968 and 6,036,635 teach related vacuum erection devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 57 $\Lambda$ -272-1000.

Samuel G. Gilbert Primary Examiner Art Unit 3735